

REMARKS

As of the date of the outstanding final Office action, claims 1, 4-6, 8-11, 14, 15, and 17-28 were pending. With this paper, Applicant hereby amends claims 10, 19, 23-25, 27, and 28. Support for the amendments may be found in the application, as filed, and no new matter is added thereby. Allowance of the claims is respectfully requested.

Claim Objections

Applicant thanks the Examiner for identifying the misnumbered claims. Accordingly, Applicant has re-numbered the claims as required under 37 C.F.R. § 1.126 and edited claims 22-25, 27, and 28 as required to reflect the appropriate parent claim. Applicant respectfully submits that the claim objection has been overcome. Reconsideration and withdrawal of the objection is respectfully requested.

Rejections Under 35 U.S.C. § 103

Claims 1, 4, 6, 9, 19, 20, and 22 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,319,221 to Savage et al. (hereinafter "Savage") in view of U.S. Patent No. 5,178,606 to Ognier et al. (hereinafter "Ognier"). Claims 10, 11, 14, 15, 17, and 18 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,447,493 to Blugerman et al. (hereinafter "Blugerman") in view of Savage. Claims 23-25 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,549,672 to Maddock et al. (hereinafter "Maddock") in view of Savage and Blugerman. Claims 26-28 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Savage in view of Ognier and further in view of Blugerman.

A. With regard to all of the pending claims, Applicant respectfully submits that the Examiner has misapplied the law related to secondary considerations in maintaining the obviousness rejections. The Examiner indicates, on pages 4 and 6 of the Final Office action, that a device such as the one claimed would have been obvious to one of ordinary skill in the art, given the teachings available in the art. This is not the appropriate analysis to dispute objective

evidence of non-obviousness. Applicant has established, through the declarations filed during the course of prosecution, (1) the long-felt need for such an invention, (2) that the long-felt need was not satisfied by anyone before the Applicant, and (3) that the invention satisfies the long-felt need. Accordingly, the Examiner must either accept the objective evidence of non-obviousness or provide a rational basis for the refusal thereof. The Examiner's assertion that the invention would simply have been obvious is not such a rational basis.

Secondary evidence is not just a cumulative or confirmatory part of the obviousness calculus but constitutes independent evidence of nonobviousness. *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1365 (Fed. Cir. 2008) (citing *Catalina Lighting, Inc. v. Lamps Plus, Inc.*, 295 F.3d 1277, 1288 (Fed. Cir. 2002)). Office personnel should consider all rebuttal evidence that is timely presented by the applicants when reevaluating any obviousness determination. MPEP § 2141(V). Rebuttal evidence may include evidence of "secondary considerations," such as "commercial success, long felt but unsolved needs, [and] failure of others," and may also include evidence of unexpected results. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). Office personnel must, as with all obviousness rejections, provide "articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) (emphasis added).

The weight attached to evidence of secondary considerations by the examiner will depend upon its relevance to the issue of obviousness and the amount and nature of the evidence. To be given substantial weight in the determination of obviousness or nonobviousness, evidence of secondary considerations must be relevant to the subject matter as claimed, and therefore the examiner must determine whether there is a nexus between the merits of the claimed invention and the evidence of secondary considerations. *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 305 n.42, 227 USPQ 657, 673-674 n. 42 (Fed. Cir. 1985), *cert. denied*, 475 U.S. 1017 (1986). The term "nexus" designates a factually and legally sufficient connection between the objective evidence of nonobviousness and the claimed invention so that the evidence is of probative value in the determination of nonobviousness. *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 7 USPQ2d 1222 (Fed. Cir.), *cert. denied*, 488 U.S. 956 (1988).

Establishing long-felt need requires objective evidence that an art recognized problem existed in the art for a long period of time without solution. The relevance of long-felt need and the failure of others to the issue of obviousness depends on several factors. First, the need must have been a persistent one that was recognized by those of ordinary skill in the art. *In re Gershon*, 372 F.2d 535, 539, 152 USPQ 602, 605 (CCPA 1967); *Orthopedic Equipment Co., Inc. v. All Orthopedic Appliances, Inc.*, 707 F.2d 1376, 217 USPQ 1281 (Fed. Cir. 1983). Second, the long-felt need must not have been satisfied by another before the invention by applicant. *Newell Companies v. Kenney Mfg. Co.*, 864 F.2d 757, 768, 9 USPQ2d 1417, 1426 (Fed. Cir. 1988). Third, the invention must in fact satisfy the long-felt need. *In re Cavanagh*, 436 F.2d 491, 168 USPQ 466 (CCPA 1971).

In this case, it is not disputed by the Examiner that a need existed, for a long period of time, for a system and method of rapidly and accurately delivering fluids in lipoplasty procedures and to fill breast implants or sizers. With regard to the first element, the Examiner indicated that the submission of the first Declaration of Dr. Mark Jewell established that such a long-felt need did indeed exist. Applicant's "Summary" of Telephone Interview dated November 29, 2011, p. 2, para. 3. Moreover, the Examiner has not contended that such a device exists. Final Office action, p. 4, 6. Accordingly, Applicant has established the long-felt need, and that no device solving that need existed at the time of the present application. With regard to the third element, the Examiner has not indicated that the invention fails to satisfy the established long-felt need. As established in the filed declarations, the claimed system and method do, in fact, solve such long-felt need.

Accordingly, only the second element of the analysis appears to be at issue. In maintaining the obviousness rejection, the Examiner simply indicates that the invention would have been obvious in view of the teachings of the art. This, however, is the type of conclusory statement disfavored by the Board and the courts. Indeed, despite that the systems of Savage and Ognier were available at the time of the present application, the declarations establish that a long-felt need for the presently claimed system and method still existed. This is precisely the scenario for which the courts and the USPTO established the mechanism for applicants to submit evidence of secondary considerations to rebut a finding of obviousness.

The Applicant has established a nexus between the claimed invention and the evidence of secondary considerations submitted in the declarations. The declarations identify the problem long-recognized in the art. Additionally, previously-attempted solutions to this problem (i.e., power IV infusers or peristaltic pumps used in conjunction with IV bags) were insufficient to solve this problem. First Supplemental Declaration Under 37 C.F.R. § 1.132 by Dr. Mark L. Jewell, M.D., dated Dec. 22, 2011, p. 4, para. 14. Only the solution proposed and claimed by the Applicant (in brief, a strain gauge system used in conjunction with a high flow rate pump) provided the *accuracy* demanded during the procedure and enabled a *reduction* in the total procedure time. Accordingly, the evidence submitted by the Applicant is extremely probative to the determination of non-obviousness. In the face of such evidence, conclusory statements that the claims would have been obvious in any event do not rise to the standard required for the Examiner to present a reasoned, articulated basis for the rejection. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. at 418.

The Applicant has established, by the initial declarations of Dr. Mark Jewell and Mr. Dan Goldberger, as well as the First Supplemental Declaration of Dr. Mark Jewell that, prior to the presently claimed systems and methods, no other available systems or methods satisfied the established long-held need. Accordingly, Applicant respectfully requests that the Examiner withdraw all rejections and allow the claims.

B. Claims 19, 20, and 22 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Savage in view of Ognier. Claim 21 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Savage in view of Ognier and Dunberger. Claims 23-25 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Maddock in view of Savage and Blugerman. The contents of the references identified above are described in the previous Amendment and Response dated January 17, 2012, and the descriptions thereof are hereby incorporated by reference herein in their entireties.

Applicant has amended claim 19 to recite “a processor for processing the electrical output from the strain gauge from time-to-time to determine the volume of fluid delivered to the implantable device without separately determining a volume of fluid removed from the implantable device.” Claim 25 has been similarly amended. Applicant respectfully submits that none of the references teach or suggest, either alone or in combination, “determin[ing] the

volume of fluid delivered to the implantable device *without separately determining a volume of fluid removed* from the implantable device.” Savage, for example, monitors and displays *both* fluid-in and fluid-out measurements, and displays this information on a monitor. Col. 3, ll. 55-57. In the event a fluid deficit (between the fluid-in and fluid-out measurements) crosses a threshold, the system warns an operator. This is true because Savage is directed at a significantly different issue – measuring the difference between fluid removed from the body and the fluid put into the body. Accordingly, monitoring fluid-out is critical to the disclosure of Savage and cannot be disregarded. None of Ognier, Dunberger, Maddock, or Blugerman, in any combination, cures this deficiency. As emphasized in the Office action, Ognier merely describes a peristaltic pump, while Dunberger merely describes PVC tubing. Maddock appears to describe monitoring fluid delivery using markings on a bag of sterile fluid, the very technique that the present application describes as undesirable. Finally, Blugerman appears to describe aspirating material from regions of the body and reaspirating fat into the body.

Therefore, Applicant respectfully submits that none of the cited references renders unpatentable amended independent claims 19 and 23, or any of the claims that depend therefrom. Accordingly, all these claims are patentable under 35 U.S.C. § 103(a) in view of the art of record. Reconsideration and withdrawal of the rejection is respectfully requested.

CONCLUSION

In view of the above, Applicant respectfully requests reconsideration and withdrawal of the remaining objections and rejections and passage of the claims to allowance. The Examiner is invited to contact Applicant's undersigned representative if the Examiner believes an interview may advance this case to allowance. Applicant's hereby authorize the Commissioner to charge any fees due in connection with the filing, or to credit any overpayment, to Deposit Account No. 13-2725, referencing docket no. 40206.0019US01.

Respectfully submitted,

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